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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,302	03/07/2001	Patrick F. Kelly	2427/1G685US1	2679

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1633

DATE MAILED: 12/05/2001

#5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,302

Applicant(s)

KELLY ET AL.

Examiner

Qian, Celine X

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-37 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a method of transducing stem cells, classified in class 435, subclass 455.
- II. Claims 17-20, drawn to a population of stem cells, classified in class 435, subclass 325.
- III. Claims 21-25, drawn to a method of stem cell transplantation, classified in class 424, subclass 93.1.
- IV. Claims 26 and 27, drawn to a method of treating a disease or disorder, classified in class 424, subclass 93.1.
- V. Claims 28-30, drawn to a non-human animal engrafted with the stem cells, classified in class 800, subclass 8.
- VI. Claims 31-37, drawn to a kit and a method for preparing said kit, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. Although the method of Group I can produce the stem cell of Group II, the stem cell can also be produced by other methods, for instance, co-culturing with producer cells. Thus, the methods and compositions of inventions of Group I and II are patentably distinct.

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Invention I and III are patentably distinct because the inventions are drawn to methods that require different starting materials and modes of operation. The method of transducing stem cells with viral vector of Group I involves different steps from the method of transplanting stem cells to an animal of Group III. Thus, the methods of inventions of Group I and III are patentably distinct.

Invention I and IV are patentably distinct because the inventions are drawn to methods that require different starting materials and modes of operation. The method of transducing stem cells with viral vector of Group I involves distinct steps from the method of treating disease or disorder. Thus, the methods of inventions of Group I and IV are patentably distinct.

Invention I and V are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting materials and modes of operation. The method of transducing stem cells of Group I does not require a non-human animal transplanted with stem cells of Group II. Thus, the methods and compositions of inventions of Group I and V are patentably distinct.

Invention I and VI are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting materials and modes of operation. The method of transducing stem cells of Group I is not limited to the use of the kit, and involves different steps from the method of making of the kit of Group VI. Thus, the methods and compositions of inventions of Group I and VI are patentably distinct.

Invention II and III are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting materials and modes of operation. Although the stem cells of Group II can be used in the method of transplantation of

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Group III, it is not limited by this use. For example, it can be induced to differentiate *in vitro* to a mature cell line. Thus, the compositions and methods of inventions of Group II and III are patentably distinct.

Inventions II and IV are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting materials and modes of operation. Although the stem cells of Group II can be used in the method of treating a disease or disorder, it is not limited by this use. For example, it can be induced to differentiate *in vitro* to a mature cell line. Thus, the compositions and methods of inventions of Group II and IV are patentably distinct.

Inventions II and V are patentably distinct because the inventions are drawn to materially distinct composition that are not directly related. The stem cells of Group II are chemically, biologically, and functionally distinct from the non-human animal of Group V. Thus, the compositions of inventions of Group II and V are patentably distinct.

Inventions II and VI are patentably distinct because the inventions are drawn to materially distinct compositions and methods that are not directly related. The stem cells of Group II are chemically, biologically, and functionally distinct from the retroviral kit of Group VI. In addition, they are not related to the method of making said kit. Thus, the compositions of inventions of Group II and VI are patentably distinct.

Inventions III and IV are patentably distinct because the inventions are drawn to methods that require different starting material and modes of operation. A method of introducing a gene to a host involves different steps than a method of treating a disease in a patient. Thus, the methods of inventions of Group III and IV are patentably distinct.

Inventions III and V are patentably distinct because the inventions are drawn to materially distinct compositions and methods are not directly related. The method of introducing a gene to a host of Group III is not limited to produce the non-human animal of Group V. It can produce an animal model to study the function of the gene of interest. Thus, the compositions and methods of inventions of Group III and V are patentably distinct.

Inventions III and VI are patentably distinct because the inventions are drawn to materially distinct compositions and methods are not directly related. The method of stem cell transplantation of Group III is not directly related to the retroviral kit of Group VI. In addition, it involves different steps than the method of making the retroviral kit. Thus, the compositions and methods of inventions of Group III and VI are patentably distinct.

Inventions IV and V are patentably distinct because the inventions are drawn to materially distinct compositions and methods that are not directly related. The method of treating a disease in a patient of Group IV does not require the non-human animal of Group V. Thus, the compositions and methods of inventions of Group IV and V are patentably distinct.

Inventions IV and VI are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting material and modes of operation. Although the kit of Group VI can be used in the method of treating a disease, it is not limited to this use. It can be used to transduce cells of any origin. In addition, the method of making the kit involves different steps than the method of treating a disease. Thus, the compositions and methods of inventions of Group IV and VI are patentably distinct.

Inventions V and VI are patentably distinct because the inventions are drawn to materially distinct compositions and methods that are not directly related. The non-human

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animal of Group V is chemically, biologically and functionally distinct from the retroviral kit of Group VI. In addition, it is not related to the method of making said kit. Thus, the compositions and methods of inventions of Group V and VI are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0823. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
December 6, 2001


REMY YUCEL, PH.D
PRIMARY EXAMINER